510(k) Summary: Cios Alpha

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:

Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:

2240869

Manufacturing Site:

SIEMENS AG Sector Healthcare
Röntgenstrasse 19 – 21
D-95478 Kemnath, Germany

Establishment Registration Number:

3002466018

2. Contact Person:

Mr. Darren Dorman
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy • Mail Code D02 • Malvern, PA 19355, USA
Phone: +1 610 219-9066 • Fax: +1 610 448-1787
Email: darren.dorman@siemens.com

3. Device Name and Classification:

Trade Name: Cios Alpha
Device: Interventional fluoroscopic x-ray system; image-intensified fluoroscopic x-ray system, mobile
Regulation Description: Image-intensified fluoroscopic x-ray system;
Regulation: Radiology

Review Panel: Radiology
Product Code: OWB, OXO
Submission Type: Traditional 510(k)
Regulation Number: 892.1650
Device Class: 2

4. **Legally Marketed Predicate Device:**

Trade Name: ARCADIS Avantic
Device: image-intensified fluoroscopic x-ray system, mobile
Regulation Description: Image-intensified fluoroscopic x-ray system.
Regulation: Radiology
Review Panel: Radiology
Product Code: OXO
Submission Type: Traditional 510(k)
Regulation Number: 892.1650
Device Class: 2

5. **Device Description:**

The Cios Alpha is a mobile fluoroscopy system designed for the surgical environment. The Cios Alpha provides comprehensive image acquisition modes to support orthopedic and vascular procedures. The system consists of two major components:

a) The C-arm with X-ray source on one side and the flat panel detector on the opposite side. The c-arm can be angulated in both planes and be lifted vertically, shifted to the side and moved forward/backward by an operator.

b) The monitor trolley providing image processing, review and patient data entry. The monitor trolley may contain an optional hardcopy (paper) printer and navigational equipment as well.

6. **Indication for Use:**

The Cios Alpha is a mobile X-Ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric patients.

7. **Substantial Equivalence:**

The Cios Alpha is substantially equivalent to the commercially available Siemens ARCADIS Avantic, cleared 06/01/2005 with K051133.
The Indication for use statement is similar to the predicate. The image intensifier has been replaced by a solid state detector. X-ray generation and control used with the

Cios Alpha is similar to the technology used with the predicate ARCADIS Avantic. A new GUI (graphical user interface) supports the user in the operation of the system.

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The Cios Alpha design is based on the ARCADIS Avantic and the experience Siemens has with more than 30 years with predicate mobile fluoroscopy C-arms (SIREMOBILE series). The advent of solid state detectors created a need to use this technology for mobile fluoroscopic systems too. The detector replaces the image intensifier and the TV camera (1k x 1k pixel matrix). The imaging system was upgraded to support the processing of up to 1536 x 1536 pixel 16bit image matrix. Full DICOM compatibility and a new graphical user interface provide networking and an intuitive operation. X-ray generation is similar to the predicate with a 25% increase in output power. Pulsed fluoroscopy, similar to the predicate, helps to reduce dose exposure for long procedures.

The following table compares the dominant performance data of the subject device with the predicate device to substantiate equivalence of both devices.

Feature	Subject Device Cios Alpha	Predicate Device ARCADIS Avantic
Mobile Fluoroscopy C-arm	Yes	Yes
Tube housing assembly with high frequency generator	Yes	Yes
kV range: 40 kV – 125 kV	Yes	Yes
Max power output	12 kV 25 kW (optional)	20 kV
Pulsed Fluoroscopy	3 mA to 120 mA (12kW) 3 mA to 250 mA (25kW)	Up to 70 mA
X-ray detector	Solid State Detector 20cm x 20cm or 30cm x 30cm	Image Intensifier with Optics and TV System 13'' diameter
Dose measurement device	Yes	Yes
Matrix size	1536 x 1536	1024 x 1024
Monitors	19'' TFT Flat Screen Display Panels, B/W or Color	18'' TFT Flat Screen Display Panels, B/W or Color
Navigation interface	Yes	Yes
Image post-processing	Yes	Yes
DICOM Functionality	Yes	Yes

9. Summary of Non-Clinical Tests:

The Siemens Cios Alpha complies with the following voluntary standards:

IEC 60601-1	60601-2-28
IEC 60601-1-1	60601-2-32
IEC 60601-1-3	60601-2-54
IEC 62366	61910-1
ISO 14971	60601-2-43
IEC 62304	IEC 60825-1
IEC 60601-1-2	IEC 10993-1
60601-2-7	NEMA PS 3.1 – 3.20 (2011)
X-Ray performance tests outlined in: 21 CFR 1020.30, 31, and 32	

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirement Specification Reviews
- Design Reviews
- Integration testing (System verification)

Non-clinical testing was conducted in accordance with Guidance for Submission of 510(k)s for Solid State X-Ray Imaging Devices (issued August 6, 1999). All test results were satisfied.

11. Summary of Clinical Tests:

For the subject of this premarket submission, Siemens did not perform a formal clinical trial but did conduct a customer use test. In this test the Cios Alpha has been evaluated in a clinical environment for 8 weeks. More than 70 patients have been examined. The following table provides a summary of the image quality outcome with different procedures:

	IQ over all	Spatial resolution	Motion resolution	Contrast	Noise
Carotids sub	Good	Good	n.a.	Acceptable	Acceptable
Vascular peripheral	Very good	Very good	n.a.	Good	Low

EVAR (AAA)	Very good	Very good	Very good	Good	Acceptable
EVAR (TAA)	Very good	Very good	Very good	Good	Acceptable

It was the investigators opinion that in this test phase the new Cios Alpha provided an even better, more detailed image quality as compared to the ARCADIS Avantic (predicate device). This includes the aortic procedures as well as the peripheral vascular structure representation i.e. the vascular representation of the foot. The complete clinical evaluation is included in the attachment.

12. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Cios Alpha is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

13. Conclusion as to Substantial Equivalence:

The Cios Alpha is intended for similar indications for use as the predicate ARCADIS Avantic. The imaging properties (X-ray source, output power and field of view) are similar. The most significant difference is the use of a solid state detector instead of an image intensifier. It is Siemens opinion, that the Cios Alpha is substantially equivalent to the ARCADIS Avantic (K051133, cleared 06/01/2005).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

Siemens Medical Solutions USA, Inc.
% Mr. Darren Dorman
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

Re: K132094
Trade/Device Name: Cios Alpha
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: II
Product Code: OWB, OXO
Dated: February 7, 2014
Received: February 11, 2014

Dear Mr. Dorman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132094

Device Name
Cios Alpha

Indications for Use *(Describe)*
The Cios Alpha is a mobile X-Ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara